

**MANUFACTURE OF MOUTHPIECE FOR TEETH SET CORRECTION**

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**Abstract of JP4028359**

**PURPOSE:**To permit easy installation of the title mouthpiece and prevent a specific tooth from being damaged, by using the mouthpiece in covering state on the whole teeth by preparing a plaster model for teeth set correction by correcting a teeth set plaster model which is prepared according to a patient's palate, and closely attaching and solidifying a softened thermoplastic polymer sheet on the model, and then demounting the solidified sheet. **CONSTITUTION:**A recessed teeth set model is made from a seal material according to a patient's palate, and plaster is introduced into the recessed model, and a projecting teeth set plaster model is prepared, and correction is applied up to a corrected form on the basis of the plaster model, and a plaster model for teeth set correction is prepared. Then, a sheet-shaped thermoplastic polymer which possesses the superior strength and the elastomer characteristic such as ethylene-vinyl acetate copolymer is heat-softened and attached on the plaster model for teeth set correction, and further closely attached through heat shaping, and the teeth set of the model is correctly printed, and the thermoplastic polymer sheet is cooling-solidified to the normal temperature and demounted, thus a mouthpiece is obtained. Since the mouthpiece possesses rubber elasticity and is not so hard, the mouthpiece can be installed reasonably on the patient's teeth set, and since the compatibility to the tooth other than the corrected tooth is superior, the force applied onto the corrected tooth can be received in dispersion by the whole of the teeth.

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Inventors: T. SHIMADA, et al.

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**Specification**

**1. Title of the Invention**

Method for producing an orthodontic mouthpiece

**2. Claims**

1. A method for producing an orthodontic mouthpiece, by which a dentition plaster cast taken from a patient having a malaligned dentition is modified to produce an orthodontic plaster cast, a softened thermoplastic polymer sheet is adhered to the orthodontic plaster cast, and then the softened thermoplastic polymer sheet is solidified and removed.

2. A method for producing an orthodontic mouthpiece according to claim 1, wherein the thermoplastic polymer has a flexure elasticity (ASTM-D747) of 800 kg/cm<sup>2</sup> or less.

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3. Detailed Description of the Invention  
[Background of the Invention]

<Field of the Invention>

The present invention relates to a method for producing an orthodontic mouthpiece for easily performing orthodontic treatment without damaging the teeth.

<Prior Art>

Conventionally, for orthodontic treatment, a method for attaching a tool for wiring normal teeth in order to apply a force to a tooth to be orthodontically-treated is generally used.

<Problems to be Solved by the Invention>

Such a method has problems in that the other normal teeth are likely to be damaged and the patient feels a pain in the wired teeth since a force is likely to be applied to a part of the teeth that are wired.

[Overview of the Invention]

<Summary>

The present inventors accumulated active studies in order to solve the above-described problems. As a result, the present inventors obtained the following knowledge and completed the present invention. By using a special mouthpiece which is completely different from that of conventional orthodontic methods, orthodontic treatment can be easily performed unlike conventional orthodontic

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methods. With the special mouthpiece, the force to be applied to the tooth to be orthodontically-treated can be held by all the teeth without damaging the other normal teeth, and the force can be especially applied only to the tooth to be orthodontically-treated.

According to the method for producing an orthodontic mouthpiece of the present invention, a dentition plaster cast taken from a patient having a malaligned dentition is modified to produce an orthodontic plaster cast, a softened thermoplastic polymer sheet is adhered to the orthodontic plaster cast, and the softened thermoplastic polymer sheet is solidified and removed.

## &lt;Effect&gt;

The orthodontic mouthpiece produced by the method according to the present invention provides the following significant effects: the mouthpiece is formed of a soft material and thus is easily attached; the mouthpiece is applied to all the teeth and thus does not cause pain to a specific tooth; and in addition, the mouthpiece can be easily removed for washing the teeth and the palate.

## [Specific Description of the Invention]

## [I] Production of an orthodontic plaster cast

## (1) Production process of a dentition model of a patient

According to a method for producing an orthodontic mouthpiece of the present invention, a concave dentition

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model is first produced from the palate of the patient for the orthodontic treatment using an impression material, and plaster is poured into the concave dentition model. Thus, an accurate convex dentition plaster cast of the patient is produced.

For producing the concave dentition model, any impression material generally used in dentistry is usable. For example, silicone impression materials, agar impression materials, and arginate impression materials are used. For the convex dentition plaster cast, it is preferable to use plaster, hard plaster or super-hard plaster.

(2) Production process of an orthodontic plaster cast

The convex dentition plaster cast of the patient produced by the above-mentioned method is used as a base and is modified into a final form or into an intermediate form to be further modified. Thus, an orthodontic plaster cast is produced.

The convex dentition plaster cast of the patient is modified to produce such an orthodontic plaster cast as follows: A portion to which a correcting force is not to be placed is bulged; and plaster is cut off from a portion on the opposite side, i.e., the portion to which a correcting force is to be placed.

For cutting, any tool which can cut plaster is usable. Generally, a bar or a hand piece used by dental technicians is used. For bulging, a composite resin, an

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epoxy resin or the like is used. For bulging, any material which has sufficient adhesive strength and tensile strength for withstanding the subsequent operations is usable.

[II] Production of an orthodontic mouthpiece

(1) Thermal molding of a thermoplastic polymer sheet

A thermoplastic polymer sheet which has been softened by heating is adhered to the orthodontic plaster cast produced by the above-described method, and more closely adhered thereto by thermal molding to accurately transfer the dentition of the orthodontic plaster cast.

The thermoplastic polymer used here needs to be superb in elastomer characteristics and in strength and also should be easily attachable.

In order to fulfill these conditions, the thermoplastic polymer used desirably has a flexure elasticity of  $800 \text{ kg/cm}^2$  (ATSM D747) or less, preferably 50 to  $500 \text{ kg/cm}^2$ .

Materials fulfilling such conditions are: ethylene-based resins such as, for example, ethylene-vinyl acetate copolymer, ethylene acrylic acid ester copolymer, ethylene methacrylic acid ester copolymer, ethylene- $\alpha$ -olefin copolymer, and polyethylene; ethylene-propylene elastomer; ethylene-propylene-diene compound-based elastomer; styrene-butadiene-based elastomer (including materials with water added thereto); polyester

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elastomer; urethane elastomer, polybutadiene; and the like.

Among these materials, it is preferable to use ethylene-based resins (especially, ethylene-vinyl acetate copolymer, ethylene- $\alpha$ -olefin copolymer, polyethylene) or styrene-butadiene-based elastomer.

These materials may be used independently, or mixed or laminated with other polymers. Various additives may also be used.

Such additives include, for example, pigments, anti-aging agents, agents to enhance the molding, stabilizers, ultraviolet-preventive agents, anti-oxidants, and abrasion-preventive agents.

The thickness of the thermoplastic polymer sheet is generally 0.25 to 3 mm, preferably 0.3 to 1.5 mm, and especially preferably 0.3 to 1 mm.

Preferable specific thermal molding methods include vacuum molding and air pressure molding, but blow molding and slash molding may also be used.

The conditions for the thermal molding vary in accordance with the method of thermal molding and the type of thermoplastic polymer.

In the case where the preferable vacuum molding or air pressure molding is used, it is necessary to soften

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the thermoplastic polymer sheet. Therefore, the sheet is heated to a temperature which is higher than or equal to the vicat softening point (JIS-K7206) of the material forming the sheet and lower than or equal to the melting point of the material forming the sheet.

The thermoplastic polymer sheet having the orthodontically-treated dentition shape accurately transferred thereon by the above-described thermal molding is cooled to room temperature or to the vicinity thereof and solidified. The sheet is removed from the dentition plaster cast. The sheet is cut along the gum line and properly shaped. Thus, a concave orthodontic mouthpiece is obtained. The sheet may be cut along about 3 mm inner to or outer to the gum line, but it is preferable that the cutting line is not in direct contact with the gum line.

In the concave orthodontic mouthpiece produced in this way, only the teeth to be orthodontically-treated are difficult to fit. However, the mouthpiece has a rubber elasticity of about 50 to 800 and is not very hard, and therefore is easily attachable to the dentition of the patient. The portions other than the tooth to be orthodontically-treated are easily fit to the respective teeth. Thus, the force to be applied to the tooth to be orthodontically-treated can be dispersed and received by all the teeth.

The mouthpiece does not have a very high hardness, and thus does not damage the orthodontic plaster cast.



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Therefore, a plurality of orthodontic mouthpieces of the same shape can be produced. It is also possible to perform the next orthodontic process, using such an orthodontic plaster cast as a base, by further modifying the cast with cutting and bulging. Such an operation can be repeated a plurality of times for straightening teeth into more normal dentition.

## [Experimental examples]

The orthodontic mouthpiece according to the present invention will be more specifically described by way of experiments of examples and comparative examples.

## Example 1

Production of a dentition plaster cast

An impression of a patient with malaligned dentition, whose two upper front teeth are to be orthodontically-treated, was produced using an alginate impression material (Starmix, produced by Nihon Shiken Corporation). Hard plaster (Diastone, produced by Mitsubishi Kogyo Cement Kabushiki Kaisha) was poured into the impression. Thus, a dentition plaster cast was produced.

Production of an orthodontic plaster cast

The upper front teeth of the dentition plaster cast were cut off by a thickness of 1 mm using a bar used by dental technicians, and a portion opposite to the portion which has been cut off was bulged by a thickness of 1 mm with an epoxy resin-based adhesive (Konishi Bond,

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produced by Konishi Co., Ltd.). Thus, an orthodontic plaster cast was produced.

Production of a thermoplastic polymer sheet

A pressed sheet having a thickness of 0.5 mm, a length of 15 cm and a width of 15 cm of an ethylene-vinyl acetate copolymer resin (Mitsubishi Polyethy-EVA "V501H", Mitsubishi Yuka Kabushiki Kaisha; flexure elasticity: 400 kg/cm<sup>2</sup>, vicat softening point: 54°C, melting point: 91°C) was placed on an absorptive precision pressure-contact device (Starback, produced by Mitsugane Kogyo Kabushiki Kaisha). When the pressed sheet was heated to a temperature of 85°C, the pressed sheet was adhered to the orthodontic plaster cast for transference.

The transferred molded body obtained by the above-mentioned transference and molding was cooled for 5 minutes by cool air from a dryer and solidified. The transferred molded body was easily removed from the plaster cast.

Production of a mouthpiece

The transferred molded body having a concave portion 2 and a convex portion 3 was cut along a line 2 mm away from the gum line of the orthodontic plaster cast by scissors. Thus, as shown in Figure 1, an orthodontic mouthpiece 1 including an upper dentition orthodontic mouthpiece 1a and a lower dentition orthodontic mouthpiece 1b, which can be separately attached to the upper teeth and the lower teeth, was

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produced. The orthodontic mouthpiece 1 was tested for the above-mentioned patient with malaligned dentition for orthodontic treatment, such that the concave portion 2 covers the patient's dentition. The orthodontic mouthpiece 1 was easily attached, and the correcting force of a portion 4 covering the surface of the dentition was applied to the two front teeth.

After the patient with malaligned dentition wore the orthodontic mouthpiece for 1 month, the orthodontic mouthpiece was removed. The orthodontic plaster cast was modified by cutting it off by another 1 mm and bulging the opposite portion by 1 mm. Thus, a second stage orthodontic plaster cast was produced.

The second stage orthodontic plaster cast was used as a base, and another thermoplastic polymer sheet was adhered thereto. Thus, a second stage orthodontic mouthpiece was produced.

The second stage orthodontic mouthpiece was tested to the patient with malaligned dentition who had finished the first stage orthodontic treatment. The second stage orthodontic mouthpiece was attachable. This indicates that the first stage orthodontic treatment was fully performed, and that the patient was now in the second stage of orthodontic treatment.

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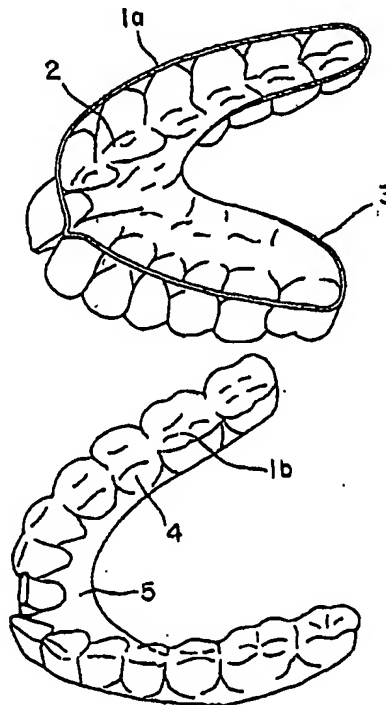
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## 4. Brief Description of the Drawings

Figure 1 represents a perspective view of an orthodontic mouthpiece according to an example of the present invention.

1 ... orthodontic mouthpiece; 1a ... upper dentition orthodontic mouthpiece; 1b ... lower dentition orthodontic mouthpiece; 2 ... concave portion; 3 ... convex portion; 4 ... portion covering the surface of the dentition; 5 ... portion covering the surface of gums.

Fig. 1



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⑮ 発明の名称 歯列矯正用マウスピースの製造法

⑯ 特 願 平2-134984

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## 明 細 書

## 1. 発明の名称

歯列矯正用マウスピースの製造法

## 2. 特許請求の範囲

1. 歯列不正患者より採取した歯列石膏模型を修正して歯列矯正用石膏模型を製作し、該歯列矯正用石膏模型に軟化した熱可塑性重合体シートを密着した後固化させて取り外すことを特徴とする歯列矯正用マウスピースの製造法。

2. 熱可塑性重合体が、曲げ弾性率

(ASTM-D747) 800 kg/cm以下のものである請求項1に記載の歯列矯正用マウスピースの製造法。

## 3. 発明の詳細な説明

(発明の背景)

## &lt;産業上の利用分野&gt;

本発明は、歯牙に傷を付けることなく歯牙に歯

列の矯正を行なうことができる歯列矯正用マウスピースの製造法に関する。

## &lt;従来の技術&gt;

従来、歯列の矯正は、一般に矯正を行なう歯牙に力を加えるために、他の正常な歯牙にワイヤー掛のための支具を装着して行なう方法が採用されている。

## &lt;発明が解決しようとする課題&gt;

しかし、このような方法では、他の正常な歯牙をも傷を付け易いばかりか、一部の歯牙にのみ特に力が加わり易いことから、ワイヤー掛された歯牙が腐むといった欠点があった。

## 〔発明の概要〕

## &lt;要旨&gt;

本発明者は上記課題を解決するために鋭意研究を重ねた結果、従来の歯列矯正方法と全く異なる特殊なマウスピースを用いることによって他の正常な歯牙を傷付けることなく、歯牙に加える力を歯牙全体でこれを保持して、矯正する歯牙のみに特に力を加えることができるので、従来の矯正

法と異なり簡単に矯正を行なうことができるとの知見を得て本発明を完成するに至った。

すなわち、本発明の歯列矯正用マウスピースの製造法は、歯列不正患者より採取した歯列石膏模型を修正して歯列矯正用石膏模型を製作し、該歯列矯正用石膏模型に軟化した熱可塑性重合体シートを密着した後固化させて取り外すことを特徴とするものである。

#### <効果>

本発明の歯列矯正用マウスピースの製造法によって製作された歯列矯正用マウスピースは、軟質材料を用いているので装着が容易であり、かつ歯牙全体に覆せて使用するので特定の歯牙を痛めることもない。また、はずして歯牙や口腔の中を清めることも容易に出来るといった著しい効果を奏する。

#### 〔発明の具体的説明〕

##### (1) 歯列矯正用石膏模型の製作

###### (1) 患者の歯列模型の製作工程

本発明の歯列矯正用マウスピースの製造法にお

いては、先ず、歯列矯正を行なう患者の口蓋より、印象材を用いて凹型の歯列模型を製作し、この凹型の歯列模型に石膏を流し込んで患者の正確な歯列の凸型の歯列石膏模型を製作する。

この凹型の歯列模型の作成に使用する印象材は、一般に歯科分野で用いられるものが使用でき、シリコン印象材、遮天印象材、アルジネート印象材等が用いられる。また、凸型の歯列石膏模型に使用する石膏は、硬質石膏、又は超硬質石膏を用いるのがよい。

###### (2) 歯列矯正用石膏模型の製作工程

上記方法によって製作された患者の歯列の凸型の石膏模型をベースにして、最終的に、あるいは段階的に矯正されるべき形にまで修正を加えて歯列矯正用石膏模型を製作する。

このような歯列矯正用石膏模型は、患者の歯列石膏模型の矯正する歯牙の矯正するべき方向の力を加えたくない部分に内張りし、その反対側の力を加えたい部分を切削して修正を行なう。

切削に使用する道具は、石膏を切削することが

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出来れば何を使用してもよいが、一般に技工用バーやハンドピースを用いて行なわれる。また肉盛りはコンポジットレジンやエポキシ樹脂等で行う。又肉盛りに使用する材料もその後の操作に耐えるだけの接合強度及び引張り強度があれば、どのようなものを使ってもよい。

##### (2) 歯列矯正用マウスピースの製作

###### (1) 熱可塑性重合体シートの熱成形

前記方法によって製作された歯列矯正用石膏模型に加熱によって軟化されたシート状の熱可塑性重合体を貼着し、さらに熱成形にて密着させて歯列矯正用石膏模型の歯列を正確に転写する。

ここで用いる熱可塑性重合体は、エラストマー特性及び強度の優れたもの、更には装着感の優れたものを用いる必要がある。

上記の条件を満たさせる為、使用する熱可塑性重合体は、曲げ弾性率 (ASTM D747) が  $800 \text{ kg/cm}^2$  以下、好ましくは  $50 \sim 500 \text{ kg/cm}^2$  のものであることが望ましい。

このような条件を満たす材料としては、エテ

レン・酢酸ビニル共重合体、エチレン・アクリル酸エステル共重合体、エチレン・メタアクリル酸エステル共重合体、エチレン・ $\alpha$ -オレフィン共重合体、ポリエチレン等のエチレン系樹脂のほかエチレン・プロピレンエラストマー、エチレン・プロピレン・ジエン化合物系エラストマー、スチレン・ブタジエン系 (水添物も含む) エラストマー、ポリエステルエラストマー、ウレタンエラストマー、ポリブタジエン等がある。

これらの中でもエチレン系樹脂 (特にエチレン・酢酸ビニル共重合体、エチレン・ $\alpha$ -オレフィン共重合体、ポリエチレン)、スチレン・ブタジエン系エラストマーを用いることが好ましい。

これらは、単独で用いても或いは他の重合体と混合したり、複層して用いても、また、各種の添加剤を添加して用いてもよい。

このような添加剤としては、顔料、老化防止剤、成形改良剤、安定剤、紫外線防止剤、酸化防止剤、摩耗改良剤等がある。

また、該熱可塑性重合体シートの厚みは、一般

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に0.25~3mm、好ましくは0.3~1.5mm、特に0.3~1mmであることが好ましい。

前記熱成形の具体的な成形法としては、真空成形や圧空成形を行なうことが好ましいが、ブロー成形やスラッシュモールド成形を行なうこともできる。

該熱成形の成形条件は熱成形の方法及び熱可塑性重合体の種類によって異なる。

望ましい熱成形である真空成形や圧空成形の場合には、前記熱可塑性重合体シートを軟化させる必要があるため、該シートを構成する素材のピカット軟化点(JIS-K7206)以上、融点以下の温度にまで加熱される。

前記熱成形によって矯正された歯列の形状を正確に転写した熱可塑性重合体シートをそのまま常態附近の温度にまで冷却して固化し、歯列石膏模型より取り外し、歯周部分を目安に切断して形状を整えることによる凹型の歯列矯正用マウスピースが得られる。この場合の切断は歯周より3mm程度内側でも外側でも良いが歯周に直接当たらない

方がよい。

このようにして製作された凹型の歯列矯正用マウスピースは矯正する歯の部分だけが嵌合し隙間になっているが、該マウスピースは50~800程度のゴム弾性を有しており、それほど硬くないので患者の歯列に無害なく咬合することができる。また、矯正する歯以外の部分は各々の歯への適合性が良いので、矯正する歯へ与える力を歯牙全体で分散して受け止めることができる。

また、該マウスピースはそれほど硬度が高くないので、歯列矯正用石膏模型を借つけることが無く、同一形状の歯列矯正用マウスピースを複数個製作できるし、この矯正歯列石膏模型をベースにして更に切削、肉盛りして修正を加えて、次の段階の矯正を行なうこともでき、このような操作を複数回繰り返してより正常な歯列に矯正することができる。

#### (実施例)

本発明の歯列矯正用マウスピースについて、更に具体的に説明するため、以下に実施例および比

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較例の実験例を示す。

#### 実施例1

##### 歯列石膏模型の製作

上前歯2本の矯正を行う歯列不正患者の印象を、アルジネート印象材(スターミックス、日本歯研工業株式会社)を用いて作成し、そこに硬質石膏(ダイヤストーン、三菱セメント株式会社)を流して歯列石膏模型を作成した。

##### 歯列矯正用石膏模型の製作

前記歯列石膏模型の前歯を技工用バーで1mmの厚さで切削すると共に、切削した箇所の反対側を、エポキシ樹脂系接着剤(コニシボンド、コニシ株式会社)にて1mmの厚さで肉盛りして歯列矯正用石膏模型を製作した。

##### 熱可塑性重合体シートの製作

エチレン・酢酸ビニル共重合体樹脂(三菱ポリエチ- EVA「V501H」、三菱油化株式会社)、曲げ弾性率400kg/cm<sup>2</sup>、ピカット軟化点54℃、融点91℃の厚さ0.5mm、縦15cm、横15cmのプレスシートを吸収倍率圧着器(スターバッ

ク三金工業株式会社)上に設置し、該プレスシートが85℃の温度になる迄昇温した時に、前記歯列矯正用石膏模型に密着させて転写を行った。

上記の如く転写して成形した転写成形体をドライヤーの冷風で5分間冷却して固化させた。この転写成形体は石膏模型より容易にとり外せた。

##### マウスピースの製作

この凹状部分2と凸状部分3とを形成した転写成形体を歯列矯正用石膏模型の歯周部位より2mm上部に合わせてハサミで切削して第1図に示すような上顎の歯列と下顎の歯列に分離して咬合することができる上顎の歯列の歯列矯正用マウスピース1aと下顎の歯列の歯列矯正用マウスピース1bとからなる歯列矯正用マウスピース1を作成した。この歯列矯正用マウスピース1を上記の矯正を行なう歯列不正患者に凹状部分2を歯列に被せて試したところ、容易に装着出来かつ、前歯2本に歯列の後面を覆う部分4の矯正の力が加わっていた。

前記歯列不正患者にこの歯列矯正用マウスピー

- 8 -

- 9 -

- 10 -

スを1ヶ月間装着した後に取り外し、上記歯列矯正用石膏模型を更に1mm切削し、その反対側の部位を1mm内嵌して修正を行ない、第2段階の歯列矯正用石膏模型を製作した。

そして、この第2段階の歯列矯正用石膏模型をベースにして再度熱可塑性重合体シートを密着させて、第2段階の歯列矯正用マウスピースを製作した。

そして、この第2段階の歯列矯正用マウスピースを前記第1段階の歯列矯正を行なった歯列不正患者に装着したところ、咬合が可能であった。これは前記第1段階の歯列矯正が十分に行なわれたことを示すもので、第2段階の歯列矯正に入ったことを意味するものである。

の歯列矯正用マウスピース、2…凹状部分、3…凸状部分、4…歯列の咬面を覆う部分、5…歯肉の咬面を覆う部分。

出願人代理人 佐 藤 一 雄

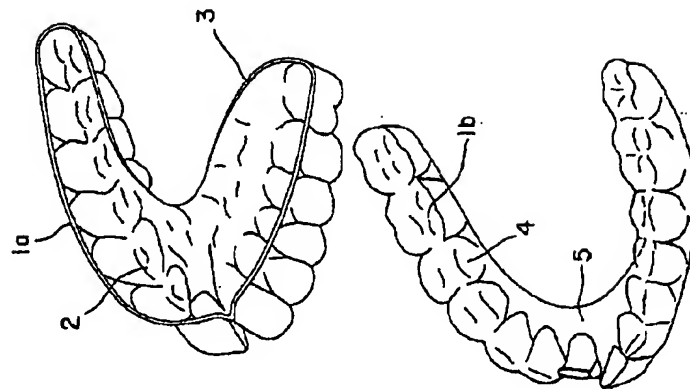
#### 4. 図面の簡単な説明

第1図は本発明実施例の歯列矯正用マウスピースの斜視図を表す。

1…歯列矯正用マウスピース、1a…上顎の歯列の歯列矯正用マウスピース、1b…下顎の歯列

- 11 -

- 12 -



第 一 図



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(Translation)

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Filing Date: May 24, 1990

Inventors: T. SHIMADA, et al.

Applicant: Mitsubishi Yuka Kabushiki Kaisha

Specification

1. Title of the Invention

Method for producing an orthodontic mouthpiece

2. Claims

1. A method for producing an orthodontic mouthpiece, by which a dentition plaster cast taken from a patient having a malaligned dentition is modified to produce an orthodontic plaster cast, a softened thermoplastic polymer sheet is adhered to the orthodontic plaster cast, and then the softened thermoplastic polymer sheet is solidified and removed.

2. A method for producing an orthodontic mouthpiece according to claim 1, wherein the thermoplastic polymer has a flexure elasticity (ASTM-D747) of 800 kg/cm<sup>2</sup> or less.

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**3. Detailed Description of the Invention**  
**[Background of the Invention]**

**<Field of the Invention>**

The present invention relates to a method for producing an orthodontic mouthpiece for easily performing orthodontic treatment without damaging the teeth.

**<Prior Art>**

Conventionally, for orthodontic treatment, a method for attaching a tool for wiring normal teeth in order to apply a force to a tooth to be orthodontically-treated is generally used.

**<Problems to be Solved by the Invention>**

Such a method has problems in that the other normal teeth are likely to be damaged and the patient feels a pain in the wired teeth since a force is likely to be applied to a part of the teeth that are wired.

**[Overview of the Invention]**

**<Summary>**

The present inventors accumulated active studies in order to solve the above-described problems. As a result, the present inventors obtained the following knowledge and completed the present invention. By using a special mouthpiece which is completely different from that of conventional orthodontic methods, orthodontic treatment can be easily performed unlike conventional orthodontic

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methods. With the special mouthpiece, the force to be applied to the tooth to be orthodontically-treated can be held by all the teeth without damaging the other normal teeth, and the force can be especially applied only to the tooth to be orthodontically-treated.

According to the method for producing an orthodontic mouthpiece of the present invention, a dentition plaster cast taken from a patient having a malaligned dentition is modified to produce an orthodontic plaster cast, a softened thermoplastic polymer sheet is adhered to the orthodontic plaster cast, and the softened thermoplastic polymer sheet is solidified and removed.

<Effect>

The orthodontic mouthpiece produced by the method according to the present invention provides the following significant effects: the mouthpiece is formed of a soft material and thus is easily attached; the mouthpiece is applied to all the teeth and thus does not cause pain to a specific tooth; and in addition, the mouthpiece can be easily removed for washing the teeth and the palate.

[Specific Description of the Invention]

[I] Production of an orthodontic plaster cast

(1) Production process of a dentition model of a patient

According to a method for producing an orthodontic mouthpiece of the present invention, a concave dentition

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model is first produced from the palate of the patient for the orthodontic treatment using an impression material, and plaster is poured into the concave dentition model. Thus, an accurate convex dentition plaster cast of the patient is produced.

For producing the concave dentition model, any impression material generally used in dentistry is usable. For example, silicone impression materials, agar impression materials, and arginate impression materials are used. For the convex dentition plaster cast, it is preferable to use plaster, hard plaster or super-hard plaster.

(2) Production process of an orthodontic plaster cast

The convex dentition plaster cast of the patient produced by the above-mentioned method is used as a base and is modified into a final form or into an intermediate form to be further modified. Thus, an orthodontic plaster cast is produced.

The convex dentition plaster cast of the patient is modified to produce such an orthodontic plaster cast as follows: A portion to which a correcting force is not to be placed is bulged; and plaster is cut off from a portion on the opposite side, i.e., the portion to which a correcting force is to be placed.

For cutting, any tool which can cut plaster is usable. Generally, a bar or a hand piece used by dental technicians is used. For bulging, a composite resin, an

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epoxy resin or the like is used. For bulging, any material which has sufficient adhesive strength and tensile strength for withstanding the subsequent operations is usable.

## [II] Production of an orthodontic mouthpiece

## (1) Thermal molding of a thermoplastic polymer sheet

A thermoplastic polymer sheet which has been softened by heating is adhered to the orthodontic plaster cast produced by the above-described method, and more closely adhered thereto by thermal molding to accurately transfer the dentition of the orthodontic plaster cast.

The thermoplastic polymer used here needs to be superb in elastomer characteristics and in strength and also should be easily attachable.

In order to fulfill these conditions, the thermoplastic polymer used desirably has a flexure elasticity of 800 kg/cm<sup>2</sup> (ATSM D747) or less, preferably 50 to 500 kg/cm<sup>2</sup>.

Materials fulfilling such conditions are: ethylene-based resins such as, for example, ethylene-vinyl acetate copolymer, ethylene acrylic acid ester copolymer, ethylene methacrylic acid ester copolymer, ethylene- $\alpha$ -olefin copolymer, and polyethylene; ethylene-propylene elastomer; ethylene-propylene-diene compound-based elastomer; styrene-butadiene-based elastomer (including materials with water added thereto); polyester

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elastomer; urethane elastomer, polybutadiene; and the like.

Among these materials, it is preferable to use ethylene-based resins (especially, ethylene-vinyl acetate copolymer, ethylene- $\alpha$ -olefin copolymer, polyethylene) or styrene-butadiene-based elastomer.

These materials may be used independently, or mixed or laminated with other polymers. Various additives may also be used.

Such additives include, for example, pigments, anti-aging agents, agents to enhance the molding, stabilizers, ultraviolet-preventive agents, anti-oxidants, and abrasion-preventive agents.

The thickness of the thermoplastic polymer sheet is generally 0.25 to 3 mm, preferably 0.3 to 1.5 mm, and especially preferably 0.3 to 1 mm.

Preferable specific thermal molding methods include vacuum molding and air pressure molding, but blow molding and slash molding may also be used.

The conditions for the thermal molding vary in accordance with the method of thermal molding and the type of thermoplastic polymer.

In the case where the preferable vacuum molding or air pressure molding is used, it is necessary to soften

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the thermoplastic polymer sheet. Therefore, the sheet is heated to a temperature which is higher than or equal to the vicat softening point (JIS-K7206) of the material forming the sheet and lower than or equal to the melting point of the material forming the sheet.

The thermoplastic polymer sheet having the orthodontically-treated dentition shape accurately transferred thereon by the above-described thermal molding is cooled to room temperature or to the vicinity thereof and solidified. The sheet is removed from the dentition plaster cast. The sheet is cut along the gum line and properly shaped. Thus, a concave orthodontic mouthpiece is obtained. The sheet may be cut along about 3 mm inner to or outer to the gum line, but it is preferable that the cutting line is not in direct contact with the gum line.

In the concave orthodontic mouthpiece produced in this way, only the teeth to be orthodontically-treated are difficult to fit. However, the mouthpiece has a rubber elasticity of about 50 to 800 and is not very hard, and therefore is easily attachable to the dentition of the patient. The portions other than the tooth to be orthodontically-treated are easily fit to the respective teeth. Thus, the force to be applied to the tooth to be orthodontically-treated can be dispersed and received by all the teeth.

The mouthpiece does not have a very high hardness, and thus does not damage the orthodontic plaster cast.

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Therefore, a plurality of orthodontic mouthpieces of the same shape can be produced. It is also possible to perform the next orthodontic process, using such an orthodontic plaster cast as a base, by further modifying the cast with cutting and bulging. Such an operation can be repeated a plurality of times for straightening teeth into more normal dentition.

**[Experimental examples]**

The orthodontic mouthpiece according to the present invention will be more specifically described by way of experiments of examples and comparative examples.

**Example 1****Production of a dentition plaster cast**

An impression of a patient with malaligned dentition, whose two upper front teeth are to be orthodontically-treated, was produced using an alginate impression material (Starmix, produced by Nihon Shiken Corporation). Hard plaster (Diastone, produced by Mitsubishi Kogyo Cement Kabushiki Kaisha) was poured into the impression. Thus, a dentition plaster cast was produced.

**Production of an orthodontic plaster cast**

The upper front teeth of the dentition plaster cast were cut off by a thickness of 1 mm using a bar used by dental technicians, and a portion opposite to the portion which has been cut off was bulged by a thickness of 1 mm with an epoxy resin-based adhesive (Konishi Bond,



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produced by Konishi Co., Ltd.). Thus, an orthodontic plaster cast was produced.

Production of a thermoplastic polymer sheet

A pressed sheet having a thickness of 0.5 mm, a length of 15 cm and a width of 15 cm of an ethylene-vinyl acetate copolymer resin (Mitsubishi Polyethy-EVA "V501H", Mitsubishi Yuka Kabushiki Kaisha; flexure elasticity: 400 kg/cm<sup>2</sup>, vicat softening point: 54°C, melting point: 91°C) was placed on an absorptive precision pressure-contact device (Starback, produced by Mitsugane Kogyo Kabushiki Kaisha). When the pressed sheet was heated to a temperature of 85°C, the pressed sheet was adhered to the orthodontic plaster cast for transference.

The transferred molded body obtained by the above-mentioned transference and molding was cooled for 5 minutes by cool air from a dryer and solidified. The transferred molded body was easily removed from the plaster cast.

Production of a mouthpiece

The transferred molded body having a concave portion 2 and a convex portion 3 was cut along a line 2 mm away from the gum line of the orthodontic plaster cast by scissors. Thus, as shown in Figure 1, an orthodontic mouthpiece 1 including an upper dentition orthodontic mouthpiece 1a and a lower dentition orthodontic mouthpiece 1b, which can be separately attached to the upper teeth and the lower teeth, was

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produced. The orthodontic mouthpiece 1 was tested for the above-mentioned patient with malaligned dentition for orthodontic treatment, such that the concave portion 2 covers the patient's dentition. The orthodontic mouthpiece 1 was easily attached, and the correcting force of a portion 4 covering the surface of the dentition was applied to the two front teeth.

After the patient with malaligned dentition wore the orthodontic mouthpiece for 1 month, the orthodontic mouthpiece was removed. The orthodontic plaster cast was modified by cutting it off by another 1 mm and bulging the opposite portion by 1 mm. Thus, a second stage orthodontic plaster cast was produced.

The second stage orthodontic plaster cast was used as a base, and another thermoplastic polymer sheet was adhered thereto. Thus, a second stage orthodontic mouthpiece was produced.

The second stage orthodontic mouthpiece was tested to the patient with malaligned dentition who had finished the first stage orthodontic treatment. The second stage orthodontic mouthpiece was attachable. This indicates that the first stage orthodontic treatment was fully performed, and that the patient was now in the second stage of orthodontic treatment.

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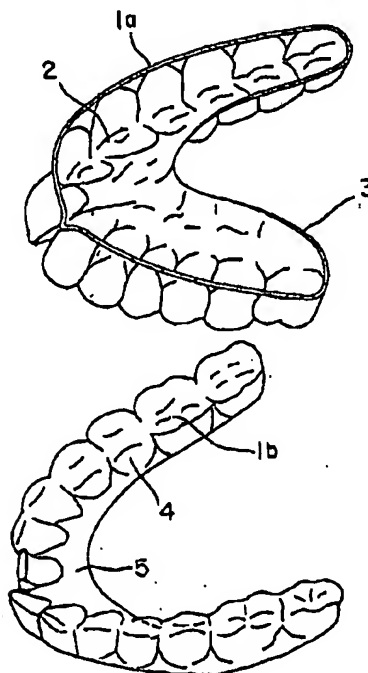
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## 4. Brief Description of the Drawings

Figure 1 represents a perspective view of an orthodontic mouthpiece according to an example of the present invention.

1 ... orthodontic mouthpiece; 1a ... upper dentition orthodontic mouthpiece; 1b ... lower dentition orthodontic mouthpiece; 2 ... concave portion; 3 ... convex portion; 4 ... portion covering the surface of the dentition; 5 ... portion covering the surface of gums.

Fig. 1



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